

### Claims

What is claimed:

- 1235 B1  
11/11/03
1. A method for controlling serum-glucose levels in a subject, said method comprising the step of administering a pharmacologically effective serum-glucose lowering amount of testosterone or the analogs, derivatives, and pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, to the subject.
2. A method according to claim 1, wherein said intramuscularly administering includes the testosterone or the analogs, derivatives, and pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, to the subject.
3. A method according to claim 1, wherein said subcutaneously administering the testosterone or the analogs, derivatives, and pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, to the subject.
- ✓ 4. A method according to claim 1, wherein said administering step includes disposing a pellet containing the testosterone or the analogs, derivatives, and pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, into the subject.

1           5.       A method according to claim 1, wherein said administering step  
2       includes applying a transdermal gel containing the testosterone or the analogs,  
3       derivatives, and pharmaceutically acceptable salts, esters, amides, and prodrugs  
4       thereof, into the subject.

1 *10/21/21* 6. A method according to claim 1, wherein the dosage of the  
2 *9* testosterone or the analogs, derivatives, and pharmaceutically acceptable salts,  
3 esters, amides, and prodrugs thereof, thereof ranges from approximately 15 mg to  
4 40 mg per day.

1           7.       A method according to claim 1, wherein said testosterone  
2       derivative comprises dihydrotestosterone.

1 8. A method for treating insulin resistance in a subject having insulin  
2 resistance, said method comprising the steps of:  
3 administering a pharmacologically effective amount of testosterone  
4 or the analogs, derivatives, and pharmaceutically acceptable salts, esters, amides,  
5 and prodrugs thereof, to the subject.

9. A method according to claim 8, wherein said intramuscularly administering includes the testosterone or the analogs, derivatives, and

3 ~~31~~ pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, to the  
4 subject.

1 10. A method according to claim 8, wherein said subcutaneously  
2 administering the testosterone or the analogs, derivatives, and pharmaceutically  
3 acceptable salts, esters, amides, and prodrugs thereof, to the subject.

1 ✓ (11) A method according to claim 8, wherein said administering step  
2 includes disposing a pellet containing testosterone or the analogs, derivatives, and  
3 pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, into the  
4 subject.

1 12. A method according to claim 8, wherein said administering step  
2 includes applying a transdermal gel containing the testosterone or the analogs,  
3 derivatives, and pharmaceutically acceptable salts, esters, amides, and prodrugs  
4 thereof, into the subject.

1 (13) A method according to claim 8, wherein the dosage of the  
2 testosterone or the analogs, derivatives, and pharmaceutically acceptable salts,  
3 esters, amides, and prodrugs thereof, ranges from approximately 15 mg to 40  
4 mg/day.

1        ✓     (14.)   A method according to claim 8, wherein said testosterone  
2        derivative comprises dihydrotestosterone.

1                15.     A method for screening a subject for insulin resistance, said method  
2        comprising the steps of:  
3                        obtaining a serum sample from the subject;  
4                        assaying the serum sample to determine both the concentration of  
5        total testosterone and the concentration of sex hormone binding globulin (SHBG)  
6        present in the sample; and  
7                        calculating a ratio of the concentration of total testosterone to the  
8        concentration of SHBG in the sample.

1                16.     A method according to claim 15, wherein a normal range in men  
2        for the ratio of total testosterone to SHBG ranges from approximately 0.7 to 1.2.

1                17.     A method according to claim 15, wherein a normal range in women  
2        for the ratio of total testosterone to SHBG ranges from approximately 0.01 to 0.03.

1                18.     A method according to claim 16, wherein an abnormal ratio in men  
2        of testosterone to SHBG is less than approximately 0.5.

1           19.     A method according to claim ~~17~~, wherein an abnormal ratio in  
2     women of testosterone to SHBG is approximately 0.06 and greater.

1           20.     A method for determining the effects of an anti-hyperglycemia  
2     treatment on a subject, said method comprising the steps of:  
3                 obtaining a serum sample from the subject;  
4                 assaying the serum sample to determine both the concentration of  
5     total testosterone and the concentration of sex hormone binding globulin (SHBG)  
6     in the sample; and  
7                 calculating the ratio of the concentration of total testosterone to the  
8     concentration of SHBG in the sample.

1           21.     A method according to claim ~~20~~, wherein a normal range in men  
2     for the ratio of total testosterone to SHBG ranges from approximately 0.7 to 1.2.

1           22.     A method according to claim ~~20~~, wherein a normal range in women  
2     for the ratio of total testosterone to SHBG ranges from approximately 0.01 to 0.03.

1           23.     A method according to claim ~~21~~, wherein an abnormal ratio in men  
2     of testosterone to SHBG is less than approximately 0.5.

1           24.    A method according to claim 22, wherein an abnormal ratio in  
2    women of testosterone to SHBG is approximately 0.06 and greater.

1           25.    A method for performing a testosterone test, said method  
2    comprising the steps of:  
3           obtaining a serum sample;  
4           assaying the serum sample to determine both the concentration of total  
5    testosterone and sex hormone binding globulin (SHBG) in the sample; and  
6           calculating a ratio of the concentration of total testosterone to the  
7    concentration of SHBG in the sample.

1           26.    A method according to claim 25, wherein a normal range in men  
2    for the ratio of total testosterone to SHBG ranges from approximately 0.7 to 1.2.

1           27.    A method according to claim 25, wherein a normal range in women  
2    for the ratio of total testosterone to SHBG ranges from approximately 0.01 to 0.03.

1           28.    A method according to claim 26, wherein an abnormal ratio in men  
2    of testosterone to SHBG is less than approximately 0.5.

1           29.    A method according to claim 27, wherein an abnormal ratio in  
2    women of testosterone to SHBG is approximately 0.06 and greater.

1 *ms 1741* 30. A method for lowering the hemoglobin A1C concentration in a  
2 subject, said method comprising the step of administering a pharmacologically  
3 effective amount of testosterone or the analogs, derivatives, and pharmaceutically  
4 acceptable salts, esters, amides, and prodrugs thereof, to the subject.

1 31. A method according to claim 30, wherein said intramuscularly  
2 administering includes the testosterone or the analogs, derivatives, and  
3 pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, to the  
4 subject.

1 32. A method according to claim 30, wherein said subcutaneously  
2 administering the testosterone or the analogs, derivatives, and pharmaceutically  
3 acceptable salts, esters, amides, and prodrugs thereof, to the subject.

1 *B2* 33. A method according to claim 30, wherein said administering step  
2 includes disposing a pellet containing the testosterone or the analogs, derivatives,  
3 and pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, into  
4 the subject.

1 34. A method according to claim 30, wherein said administering step  
2 includes applying a transdermal gel containing the testosterone or the analogs,

LIC-10002/03  
81124gs

3 ~~B2C-A~~ derivatives, and pharmaceutically acceptable salts, esters, amides, and prodrugs  
4 thereof, into the subject.

1 ~~B2C-A~~ 35. A method according to claim 30, wherein the dosage of the  
2 testosterone or the analogs, derivatives, and pharmaceutically acceptable salts,  
3 esters, amides, and prodrugs thereof, thereof ranges from approximately 15 mg to  
4 40 mg per day.

1 36. A method according to claim 30 wherein said testosterone  
2 derivative comprises dihydrotestosterone.

1 ~~B2C-A~~ 37. A method for treating Syndrome X in a subject having Syndrome  
2 X, said method comprising the step of administering a pharmacologically effective  
3 amount of testosterone or the analogs, derivatives, and pharmaceutically  
4 acceptable salts, esters, amides, and prodrugs thereof, to the subject.

1 38. A method according to claim 37, wherein said intramuscularly  
2 administering includes the testosterone or the analogs, derivatives, and  
3 pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, to the  
4 subject.



B2  
ep+  
Office+

1 39. A method according to claim 37, wherein said subcutaneously  
2 administering the testosterone or the analogs, derivatives, and pharmaceutically  
3 acceptable salts, esters, amides, and prodrugs thereof, to the subject.

1 40. A method according to claim 37, wherein said administering step  
2 includes disposing a pellet containing the testosterone or the analogs, derivatives,  
3 and pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, into  
4 the subject.

1 41. A method according to claim 37, wherein said administering step  
2 includes applying a transdermal gel containing the testosterone or the analogs,  
3 derivatives, and pharmaceutically acceptable salts, esters, amides, and prodrugs  
4 thereof, into the subject.

1 42. A method according to claim 37, wherein the dosage of the  
2 testosterone or the analogs, derivatives, and pharmaceutically acceptable salts,  
3 esters, amides, and prodrugs thereof, thereof ranges from approximately 15 mg to  
4 40 mg per day.

1 43. A method according to claim 37, wherein said testosterone  
2 derivative comprises dihydrotestosterone.

1 *10/1/02* 44: A method for identifying and treating insulin resistance in a subject  
2 having insulin resistance, said method comprising the steps of:  
3 obtaining a serum sample from the subject;  
4 assaying the serum sample to determine both the concentration of total  
5 testosterone and the concentration of sex hormone binding globulin (SHBG)  
6 present in the sample;  
7 calculating the ratio of the concentration of total testosterone to the  
8 concentration of SHBG in the sample; and  
9 administering a pharmacologically effective amount of testosterone or the  
10 analogs, derivatives, and pharmaceutically acceptable salts, esters, amides, and  
11 prodrugs thereof to the subject if the ratio of the concentration of total testosterone  
12 to the concentration of SHBG globulin in a male subject is less than  
13 approximately 0.5 and for a female subject is approximately 0.06 and greater.

1 ✓ 45) The method according to claim 44, wherein the testosterone  
2 derivative comprises dihydrotestosterone.

1 *10/1/02* 46. A method according to claim 44, wherein said intramuscularly  
2 administering includes the testosterone or the analogs, derivatives, and  
3 pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, to the  
4 subject.

1 105 B2  
2 47. A method according to claim 44, wherein said subcutaneously  
3 administering the testosterone or the analogs, derivatives, and pharmaceutically  
4 acceptable salts, esters, amides, and prodrugs thereof, to the subject.

1 ✓ (48) A method according to claim 44, wherein said administering step  
2 includes disposing a pellet containing the testosterone or the analogs, derivatives,  
3 and pharmaceutically acceptable salts, esters, amides, and prodrugs thereof, into  
4 the subject.

1 49. A method according to claim 44, wherein said administering step  
2 includes applying a transdermal gel containing the testosterone or the analogs,  
3 derivatives, and pharmaceutically acceptable salts, esters, amides, and prodrugs  
4 thereof, into the subject.

1 105 B2  
2 (50) A method according to claim 44, wherein the dosage of the  
3 testosterone or the analogs, derivatives, and pharmaceutically acceptable salts,  
4 esters, amides, and prodrugs thereof, thereof ranges from approximately 15 mg to  
5 40 mg per day.